CHARGE: 502(f)(1)—the labeling of the *aspirin tablets*, while held for sale, failed to bear adequate directions for use since, in lieu of a dosage statement for children under 3 years of age, the labeling failed to state that for the 3-year and under age group a physician should be consulted; and 502(f)(2)—the labeling of the *oil of wintergreen* and the *aspirin tablets*, while held for sale, failed to bear warnings against misuse by children since their labelings failed to warn that such articles should be kept out of reach of children.

DISPOSITION: 11–22–57. Consent—claimed by Dr. Sachs Laboratories and relabeled.

**5469. Herb tea.** (F.D.C. No. 40933. S. No. 49–037 M.)

QUANTITY: 133 4-oz. boxes at Chicago, Ill., in possession of W. W. Laboratories.

SHIPPED: During April 1957, from New York, N.Y.

LABEL IN PART: (Box) "Hartz Mountain Brand Herb Tea"; (bulk drum) "Special Cut & Sifted Tea Mixture Formula 68 Containing the following: Alex Senna, Mandrake, Elder Flowers, Aniseed, Fennel Seed, Red Clover Tops, Linden Flowers and Leaves, Dog grass, Sassafras Bark of Root Natural, Uva Ursi."

RESULTS OF INVESTIGATION: The article was shipped, as described above, in bulk drums; and, upon receipt at Chicago, it was repackaged and labeled by the consignee.

LIBELED: 11–7–57, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the box label of the article contained false and misleading representations that the article was an adequate and effective treatment for regulating the stomach, providing perfect health, enabling one to achieve a ripe old age, and eliminating constantly accumulating body poisons; 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient; and 502(f)(2)—the article was essentially a laxative, and its labeling failed to bear adequate warnings against excessive use as a laxative and against use where symptoms of appendicitis are present.

DISPOSITION: 12–5–57. Default—destruction.

## DRUGS FOR VETERINARY USE

**5470. C-Ran and Stil-Ran.** (F.D.C. No. 40706. S. Nos. 70–281/2 M.)

QUANTITY: 87 boxes, 6 vials each, of *C-Ran*, and 77 boxes, 5 vials each, of *Stil-Ran*, at Wayne, Pa.

SHIPPED: Between 5–23–57 and 9–12–57, from Baltimore, Md., by Morjac Co.

LABEL IN PART: (Box) "C-Ran * * * Each Ampoule Contains 6 cc. Ascorbic Acid Solution In the Form of Sodium Ascorbate Equal to 2 gm. Ascorbic Acid (40,000) Units Vitamin C" and "Stil-Ran * * * Diethlystilbestrol Solution."

LIBELED: 10–18–57, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the box labels of the articles contained false and misleading representations that the *C-Ran* was effective for overcoming breeding difficulties in cows and that the *Stil-Ran* was effective for treating the condition of retained placenta in cows; and 502(f)(1)—the *Stil-Ran* was a drug which was not safe for animal use except under the supervision of a licensed veterinarian, and the label failed to bear the statement "Caution:

Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

DISPOSITION: 11–18–57. Default—destruction.

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

**5471. Digitoxin powder (2 seizure actions).** (F.D.C. Nos. 40514, 40515. S. Nos. 62–014 M, 62–019 M.)

QUANTITY: 5 aluminum btls., 2 containing 5 grams and 3 containing 10 grams, at New York, N.Y., and 1 aluminum btl. containing 41.37 grams, at Long Island City, N.Y.

SHIPPED: 11–16–56, from Paris, France, by Labomial L. M.

LABEL IN PART: "Labomial Digitoxin U.S.P."

RESULTS OF INVESTIGATION: Examination showed that the 5-btl. lot of the article contained not more than 84.6 percent digitoxin and that the 1-btl. lot contained not more than 82.8 percent digitoxin.

LIBELED: 7–17–57 and 7–23–57, E. Dist. N.Y., and S. Dist. N.Y.

CHARGE: 501(b)—the strength of the article, when shipped, differed from the standard for digitoxin set forth in the United States Pharmacopeia since it contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 10–17–57 and 10–18–57. Default—destruction.

**5472. Digitoxin tablets.** (F.D.C. No. 40659. S. No. 68–969 M.)

QUANTITY: 1 drum containing 57,200 tablets at Hempstead, N.Y.

SHIPPED: Between 3–24–53 and 3–7–56, from France.

LABEL IN PART: "Digitoxin 0.1 mg. Pink."

RESULTS OF INVESTIGATION: The shipment consisted of digitoxin powder, which was used in preparing the above-described tablets.

Examination showed that the tablets contained not more than 83 percent of the declared amount of digitoxin.

LIBELED: 10–2–57, E. Dist. N.Y.

CHARGE: 501(b)—while held for sale, the strength of the article differed from the standard for *digitoxin tablets* set forth in the United States Pharmacopeia since the article contained less than 90 percent of the declared amount of digitoxin.

DISPOSITION: 10–25–57. Default—destruction.

**5473. Dextro-amphetamine sulfate timed disintegration capsules.** (F.D.C. No. 40568. S. No. 62–813 M.)

QUANTITY: 54 100-capsule btls. at Jersey City, N.J.

SHIPPED: 10–30–56, from Long Island City, N.Y., by Nysco Laboratories, Inc.

RESULTS OF INVESTIGATION: Examination showed that the article contained 142 percent of the labeled amount of dextro-amphetamine sulfate and released 64 percent of its dextro-amphetamine sulfate ingredient during the first hour.

LIBELED: 8–15–57, Dist. N.J.

CHARGE: 501(c)—the strength and quality of the article, when shipped, differed from that which it purported to possess since it contained more than

*See also No. 5464.